



Eminent Spine, LLC

7200 N IH 35 Bldg. 1 Georgetown, TX 78626

Phone: (512) 868-5980 Fax: (512) 864-1462

APR 22 2010

510(k) Summary

Date: 16 April 2010

Sponsor: Eminent Spine LLC
7200 N I-35 Building #1
Georgetown, TX 46037
Phone 512-868-5980
Fax 512-864-1462

Contact Person: Dave Freehill, President

Proposed Trade Name: Diamondback™ Spinal System

Device Classification Class II

Classification Name: Pedicle screw spinal system

Regulation: 888.3070

Device Product Code: MNI, MNH

Device Description: The Diamondback™ Spinal System consists of rods, monoaxial and polyaxial screws with caps, and cross connectors with lock screws. Rods are available either straight or pre-contoured in a variety of lengths. Monoaxial and polyaxial screws are available in a variety of diameter-length combinations.

Intended Use: The Diamondback™ Spinal System is designed to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments as an adjunct to fusion in skeletally mature patients. The system is intended for posterior, pedicle fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra. In addition, when used as a pedicle screw fixation system of the non-cervical posterior spine (T1 to S2) the system is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

Materials: The Diamondback™ Spinal System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Devices: CD HORIZON® (K031655/K041460)
Moss Miami (K992168/K022623)
Synergy VLS (K950099/K974749)

**Technological
Characteristics:**

The Diamondback™ Spinal System possesses the same technological characteristics as the predicate devices. These include basic design (rod-based pedicle screw system having monoaxial and polyaxial screws), material (titanium alloy), sizes (rod and screw sizes are encompassed by those offered by the predicate systems) and intended use (as described above). The fundamental scientific technology of the Diamondback™ Spinal System is the same as previously cleared devices.

Performance Data:

Static compression bending and torsion and dynamic compression bending of the worst case Diamondback™ Spinal System construct was performed according to ASTM F1717. The mechanical results demonstrated that the Diamondback™ Spinal System performs as well as or better than the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Eminent Spine LLC
% BackRoads Consulting Inc.
Karen E. Warden, Ph.D.
President
8202 Sherman Road
Chesterland, Ohio 44026-2141

APR 22 2010

Re: K100377

Trade/Device Name: Diamondback™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: February 04, 2010
Received: February 12, 2010

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkersen".

Mark N. Melkersen

Director

Division of Surgical, Orthopedic

And Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K100377

Device Name: **Diamondback™ Spinal System**

Indications for Use:

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Prescription Use X

AND/OR


Over-the-Counter Use

(21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100377